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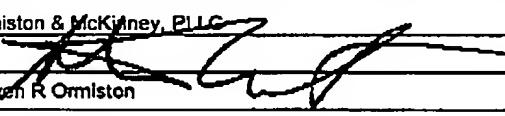
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		Application Number	10/815,408
		Filing Date	Apr. 1, 2004
		First Named Inventor	P. Gardner et al.
		Art Unit	3636
		Examiner Name	Joseph F. Edell
Total Number of Pages in This Submission	7	Attorney Docket Number	02-014-01 (IDRF118)

ENCLOSURES (Check all that apply)

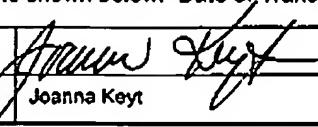
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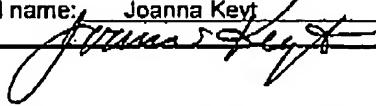
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors: P. Gardner et al.)	Attorney
Serial No: 10/815,408)	Docket No: 02-014-01(idrf118)
Filed: April 1, 2004)	Group Art Unit: 3636
Title: Infant Holder)	Examiner: Joseph F. Edell
)	Confirmation No.: 7986
)	

APPELLANTS/APPLICANTS' REPLY TO THE EXAMINER'S ANSWER

Before specifically addressing the new issues and arguments raised in the Examiner's Answer, the Applicants wish to note that the devices of Bowman and Powell are so different from the claimed infant holder that, as a general proposition, it just does not seem credible to assert Bowman teaches the infant holder of Claims 1-4 or that the combination of Bowman and Powell teaches the infant holder of Claims 5-11. As stated in the Specification:

"Embodiments of the invention are directed to an infant holder for circumcision and other medical procedures that helps an infant to lie in a natural, comfortable position with legs flexed at the hips and knees and rotated at the hips, while still allowing the doctor good access to the infant's groin area." (Specification paragraph 0007.)

"As best seen in Fig. 5, base 18 of torso recess 14 is inclined at an angle 29 which, in the embodiment illustrated in the figures, is about 10° [Claim 11]. Inclining base 18 keeps the infant's head above his feet to help prevent aspiration. The incline, however, should be slight so that the infant's head and torso do not unduly pressure the legs. It is expected that an incline angle 29 in the range of 5° to 20° [Claim 7]

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without unduly pressuring the infant's legs." (Specification paragraph 0009.)

"Leg recesses 16 are positioned near the lower portion of torso recess 14. As best seen in Fig. 3, an upper/thigh portion 30 of each leg recess 16 extends away from torso recess 14 at an angle 31 which, in the embodiment illustrated in the figures, is about 90° [Claims 2, 8, 9 and 11]. ... In addition, as best seen in Fig. 6, leg recess base 22 is inclined relative to torso recess base 18 in upper portion 30 at an angle 33 which, in the embodiment illustrated in the figures, is about 30° [Claims 2, 8, 9 and 11]. This configuration allows the infant's hips to flex more naturally when the infant is supported in holder 10. It is expected that a hip bend angle 31 in the range of 70° to 120° and a hip incline angle 33 in the range of 20° to 50° will mimic the natural flexure in the hips of most infants [Claims 1, 6 and 10]." (Specification paragraph 0010.)

Neither Bowman nor the combination of Bowman and Powell *help* an infant to lie in a natural, comfortable position. Like any flat surface, Bowman *allows* an infant to lie in a natural position unless and until the infant's legs are strapped down against torso pad 40. In Powell, the infant is strapped down in a completely unnatural and uncomfortable position. It necessarily follows, therefore, that neither Bowman nor the combination of Bowman and Powell teach all of the elements of the claims.

1. Bowman's Torso Pad Does Not "Inherently" Support An Infant's Legs

The Examiner states at page 6 of the Answer that Bowman's "torso pad clearly supports the infant's torso and must inherently support the infant's legs as the infant's legs are attached to the infant's torso." This is one of those arguments seen only rarely that is so fundamentally unreasonable that a response is difficult to formulate. According to the Examiner's logic, any surface on which an infant lies on his back may be deemed to be configured to support an infant's legs at the claimed range of angles even though the infant's legs don't touch the surface because, of course, these angles reflect the natural position of an infant lying on his back.

One response to this line of reasoning, one would suppose, had it been presented during prosecution, would be to amend the claims to recite that the recess

be configured to "directly" support the infant's legs. Of course, Applicants cannot now present such an amendment even if they were so inclined. Fortunately, such an extreme measure is not necessary. Claim 1 requires a recess configured to support an infant's torso *and* legs. The clear implication is that Claim 1 requires direct support for both the torso and the legs -- indirectly supporting the legs through the torso does not meet the plain language of the claim. A contrary reading of Claim 1 would render nugatory the recitation of support for both the infant's torso and the infant's legs.

2. Bowman's Device Does Not Support The Infant's Legs

The Examiner states at page 6 of the Answer that "Figure 1 of Bowman shows that the infant's legs are supported by the recess formed in the torso pad 40 when the infant is lying in the infant holder." This statement is not correct. It is not possible to tell from the plan view of Bowman's Fig. 1 whether or not the infant's legs are supported by or even touching any part of torso pad 40. However, it is clear from the section view of Fig. 2, which is taken along the line 2-2 in Fig. 1, that the infant's legs are not supported by torso pad 40. Indeed, the infant's legs do not even touch torso pad 40. Fig. 2 in Bowman shows the legs suspended over torso pad 40. The Examiner admits as much by resorting to the line of reasoning discussed above in Section 1.

Lower torso support block 50 in Bowman also is not configured to nor does it support the infant's legs. Bowman Figs. 1 and 2 show lower torso support block 50 in contact with the infant's buttocks. Even if it is assumed for purposes of argument only that the infant's "lower leg portion" contacts lower torso support block 50, as suggested by the Examiner, any such contact cannot reasonably be deemed support for the infant's legs in general, and more specifically, support for the infant's legs at the claimed range of angles. Indeed, it is evident from Bowman Fig. 2 that pressing down on the infant's knees will cause his legs to flex down toward torso pad 40. There is simply no support for the infant's legs in Bowman's device.

3. A Recess Configured To Support An Infant's Torso And Legs Is Not A Statement Of Intended Use.

The Examiner states at page 6 of the Answer that:

"The configuration of the recess to support an infant's torso and legs in the recited angular orientations is merely intended use. The infant holder of Bowman is capable of performing the intended use, and, therefore, it meets the claim."

These statements are insufficient to support the rejection for two reasons.

First, whether the noted claim language is deemed to be structural or functional, it is not merely a recitation of intended use. The phrase "configured to support an infant's torso and legs" modifies "recess" – the recess in the body must have this characteristic to meet the limitations of Claim 1. This is no less a structural limitation on the recess simply because it suggests this part of the body will be used to support an infant's torso and legs. To the extent "configured to support an infant's torso and legs" might be deemed a functional limitation on the recess, it is well settled that any such functional limitation is proper and must be accorded patentable weight. See e.g., *In re Mills*, 916 F.2d 680, 16 USPQ.2d 1430, 1433 (Fed. Cir. 1990); *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976) ("members adapted to be positioned" serve to precisely define present structural attributes of interrelated component parts of the claimed assembly); *In re Swinehart*, 439 F.2d 210 (CCPA 1971).

Although the Examiner does not cite to any legal authority to support his position, he is apparently relying on the often used and much abused *Ex parte Masham* cited in MPEP § 2114. Quoting Masham, MPEP § 2114 says that "[a] claim containing a 'recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus' if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (BPAI 1987)." Any such reliance on Masham is misplaced.

In Masham, the Board held that the recitation in the preamble of the material intended to be worked on by a claimed apparatus did not impose any structural limitations which differentiate it from a prior art apparatus satisfying the structural

limitations of the claim. The Board then went on to state more broadly (and quite unnecessarily) that the "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus" Even this broad language in Masham has never been construed as a ban on functional limitations -- see *In re Mills*, *In re Venezia* and *In re Swinehart* cited above. Rather, the holding in Masham is limited to statements of intended use for "a claimed apparatus." Claim 1 is directed to an infant holder having a body with a recess -- an article of manufacture. The recess "configured to support an infant's torso and legs" is not a statement of intended use for "a claimed apparatus" as in Masham or even for the claimed article. Rather, it is a limitation that quite properly defines the recess in the body of the claimed infant holder.

Second, as noted above in detail in Section 2, the device of Bowman is not capable of supporting the infant's legs as claimed. The Examiner's assertion to the contrary is not correct.

4. The Claimed Angles Are Not Obvious Design Choices.

The Applicants have discovered that if the infant is supported in a natural position, then he can be immobilized in this natural position for circumcision and other medical procedures. The Applicants quantified this natural position and then designed (and claimed) an infant holder to support the infant in this natural position so that the infant could be immobilized in this same position for circumcision. While this may seem easy enough *in hindsight*, the plain fact is that none of the cited references teach or even remotely suggest either the discovery, the quantification, or the design. On the contrary, Powell teaches a device in which the infant is strapped down in a most unnatural position. Bowman teaches a device in which the infant is allowed to lie in a natural position, just as if he were lying on the floor, unless and until the infant's legs are strapped down to immobilize the infant for circumcision.

The Examiner's reliance on *In re Aller* and "obvious matter of design choice" (another new grounds for rejection) is misplaced. *In re Aller* is cited in MPEP § 2144.05 II.A in support of the proposition that "[g]enerally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration

or temperature is critical." The claims at issue in this case don't have anything to do with concentrations or temperatures. So far as Applicants are aware, the courts have not extended the "obvious matter of design choice" doctrine to mechanical articles of manufacture.

This section of the MPEP goes on to quote from Aller: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). According to the MPEP, *In re Aller* actually held that the claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was *prima facie* obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%. The facts of *In re Aller* are wholly unrelated to the facts of the instant application, as is its holding. Even if the more general statement noted above is taken out of context and applied to a mechanical article of manufacture, it has no application to this case-- the prior art in this case does not disclose "the general conditions of a claim" from which an optimum or workable range might be discovered by routine experimentation. Indeed, neither Bowman nor Powell disclose any range of angles, or even mention the significance of supporting the infant's legs at any particular angle.

Respectfully submitted,

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